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IN THE

Supreme Court of the United States

OCTOBER TERM, 1970

No. 717

DERBY FOODS, INC., *Petitioner*

v.

FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, *Respondent*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

INTRODUCTION

Derby Foods, Inc., petitioner in this proceeding, respectfully petitions the Court for a Writ of Certiorari to review a judgment of the United States Court of Appeals for the Third Circuit, *Derby Foods, Inc. v. Food and Drug Administration, U.S. Department of HEW*, 427 F.2d 511 (3rd Cir. 1970).

JURISDICTIONAL STATEMENT

This petition for a Writ of Certiorari seeks review of a judgment of the United States Court of Appeals for the Third Circuit, *Derby Foods, Inc., supra,* dated May 14, 1970, affirming an order of the Food and Drug Administration which was published in the Federal Register of July 24, 1968, 33 F.R. 10506 (corrected on July 27, 1968, 33 F.R. 10713). On June 22, 1970, the Court of Appeals entered an order denying petitioner's Petition for Rehearing. The jurisdiction of the Court to review the important question of federal law presented in this petition is invoked under 28 U.S.C. §1254(1), 28 U.S.C. §2350, 28 U.S.C. §2101 (e), and 21 U.S.C. §371(f)(4).

QUESTION PRESENTED FOR REVIEW

Whether, under the Administrative Procedure Act, 5 U.S.C. §557(e)(A), the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §371(e)(3), and the decisions of this Court, it is required, in a rule making proceeding directed by statute to be made on the record after an opportunity for a hearing, that the Food and Drug Administration set forth findings of fact which provide reasons or basis supporting its rejection of a fundamental and material issue of fact raised by objections and by the evidence of record presented at the hearing?

STATUTES AND REGULATIONS INVOLVED

The following statutes and regulation are involved in this case: The Administrative Procedure Act, 80 Stat. 383 (1966), 5 U.S.C. §553(c); 80 Stat. 387 (1966), 5 U.S.C. §557(e)(A); 80 Stat. 388 (1966), as amended, 5 U.S.C. §559; the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1042 (1938), as amended, 21 U.S.C. §331 (a) and (b); 52 Stat. 1046 (1938), as amended, 21

U.S.C. §341; 52 Stat. 1047 (1938), as amended, 21 U.S.C. §343(g); 52 Stat. 1055 (1938), as amended, 21 U.S.C. §371(e), and (f); and 21 C.F.R. §46.1* (33 F.R. 10506-10510, as corrected in 33 F.R. 10713). Their pertinent text is set forth in the appendix attached hereto.

STATEMENT OF THE CASE

Petitioner, a corporation incorporated under the laws of the State of Illinois, is engaged in the business of manufacturing and distributing in interstate commerce Peter Pan Peanut Butter. Petitioner's Peter Pan brand has been marketed commercially since the early 1930s. Commencing in 1957 and continuing to the present time, the Peter Pan formulation has consisted of 87% peanuts, 9.6% dextrose, 1.7% stabilizer, and 1.7% salt. The record reveals that this formulation ranks second in national sales of peanut butter, with approximately 14% of the total national market. The best selling peanut butter formulation is Skippy, produced by Corn Products Company, with approximately 22% of the total national market.** The Skippy formulation consists of 3¾% salt and sugar, 8½% partially hydrogenated peanut oil and 87¾% peanuts***, as the concept of "peanuts" is defined by the Standard.

On July 24, 1968, the Food and Drug Administration published in the Federal Register, 33 F.R. 10506-10510,

* This regulation has been stayed in its entirety pending judicial review (33 F.R. 16333, November 7, 1968).

** The market percentages of Peter Pan and Skippy are based on data collected in 1965. There is no reason to believe that their respective market positions, as the number one and two selling brands, have changed since 1965.

*** In this petition, the Peter Pan and Skippy formulations will collectively be referred to as containing 87% peanuts and 13% optional ingredients.

an order captioned "Peanut Butter, Definition and Standard of Identity; Findings of Fact, Conclusions, and Final Order." This order, dated July 8, 1968, was signed by Winton B. Rankin, who was then Deputy Commissioner of Food and Drugs, and was purportedly promulgated pursuant to Section 401 (21 U.S.C. §341) and Section 701 (21 U.S.C. §371) of the Federal Food, Drug, and Cosmetic Act (Act).

The administrative action which ultimately culminated in the July 8, 1968 order (Order) commenced on July 2, 1959, when a "Notice of Proposed Rule Making" to establish a definition and standard of identity for peanut butter was published in the Federal Register on the initiative of the Commissioner of the Food and Drug Administration. The specifications of this proposal would have limited the optional ingredient content of peanut butter to 5% of the weight of the finished food (95% peanuts). Subsequently, the Agency issued (1) a "Final Order," dated November 28, 1961, defining peanut butter as a product containing not less than 90% peanuts (later stayed in its entirety), (2) a "Proposed Modification of Standard of Identity" for peanut butter, dated November 10, 1964, and (3) a second "Final Order" establishing a definition and standard of identity for peanut butter, dated July 8, 1965. The 10% optional ingredient limitation, which made its initial appearance in the 1961 order, was perpetuated in all subsequent proposals and orders.

Petitioner has been an interested and adversely affected party since the issuance of the original proposal of July 2, 1959, and submitted timely comments and objections to every proposal and order subsequently published by the Agency. From the beginning, Derby has consistently objected to the quantitative limitations which were placed on the amount of optional in-

gredients that would be permitted in peanut butter—first 5% and later 10%—and has consistently urged that the optional ingredient level should be set at 13% so as to embrace the formulation Derby produced and for which a substantial proportion of American consumers had demonstrated a decided preference.

On September 4, 1965, an order was published in the Federal Register, which stayed in its entirety the definition and standard of identity for peanut butter as published on July 8, 1965 pending a public hearing under the provisions of Section 701(e)(3), of the Act. Announcement of this public hearing, which "was to be held for the purposes of receiving evidence relevant and material to the issues raised by the objections filed" to the definition and standard of identity for peanut butter, was published on September 18, 1965. This announcement recited that the objections, which had been previously filed to the stayed standard, provided reasonable grounds for a hearing on specified issues.

A material issue raised by Derby's objections to the order, and upon which Derby and other participants at the hearing presented substantial evidence of record, concerned the unreasonableness of the order in limiting the optional ingredients in peanut butter to 10% of the weight of the finished food. This limitation had the effect of excluding from the regulatory definition of peanut butter Derby's consumer-preferred formulation which contained 13% optional ingredients (87% peanuts). The question concerning the reasonableness of a 10% optional ingredient level, as opposed to 13%, was a material issue throughout the proceeding, and was recognized as such in the Issues verbalized by the Hearing Examiner:

> I would now dictate for this record those issues which will be heard at the forthcoming hearing . . .

(3) Will it promote honesty and fair dealing in the interest of consumers, and is it reasonable to

(a) Limit the optional ingredients to 10 percent of the weight of the finished food as set forth in Section 46.1(a) of the standard, or should the percentage of the optional ingredients be increased or decreased? And if so, to what percentage of the weight of the finished food? (R. 244, 245)

Included in the evidence of record was undisputed testimony that the addition of stabilizing and seasoning ingredients to peanut butter has improved the palatability, texture, appearance, spreadability and shelf life of the product. The evidence of record also established that consumers buy a particular brand of peanut butter because of its overall qualities, which include palatability, shelf life, freshness, texture, spreading attributes and aroma. Consumers do not select peanut butters on the basis of the amount of peanuts employed in a particular formulation, nor do consumers have any expectations that peanut butter contains 90% peanuts or any other specified level. The uncontradicted evidence of record reveals that Derby's peanut butter formulation, containing 87% peanuts and 13% stabilizing and seasoning ingredients, possesses attributes preferred by vast numbers of consumers, and that, when measured by any parameter relevant to peanut butter, possesses all of the organoleptic, compositional and nutritional qualities considered essential to peanut butter.

Allegedly based upon the evidence received at the hearing, on December 6, 1967, there was published in the Federal Register, 32 F.R. 17482, "Proposed Findings of Fact and [a] Tentative Order." Exceptions and comments to this order were invited and were submitted by petitioner herein. Petitioner's exceptions

pointed out that the Tentative Order failed to explain why a 13% level of optional ingredients should not be embraced within the standard of identity.

Subsequently, on July 24, 1968, the Commissioner published "Findings of Fact, Conclusions, and Final Order." The Final Order, as had the 1967 Tentative Order, limited the optional ingredients in peanut butter to 10% of the weight of the finished food. No factual findings were made incident to the issuance of the Final Order explaining how the evidence of record justified the rejection of a 13% optional ingredient limitation. No factual findings were made specifying the basis upon which the Agency had concluded that it was in the public interest and reasonable to preclude the continued availability of petitioner's and Corn Product's formulations, the two most popular peanut butter formulations. Indeed, the evidence of record would not support any such findings.

Pursuant to Section 701(f) of the Act [21 U.S.C. §371(f)], and Rule 15(a) of the Federal Rules of Appellate Procedure, petitioner, on October 18, 1968, filed with the United States Court of Appeals for the Seventh Circuit a Petition for Review. On January 2, 1969, on motion of the Government and pursuant to 28 U.S.C. §2112(a), that court entered an order transferring the proceeding for judicial review to the United States Court of Appeals for the Third Circuit, where a similar Petition for Review had been filed by Corn Products Company. On September 29, 1969, the cases were argued before Circuit Judges Staley, Seitz and Stahl of the United States Court of Appeals for the Third Circuit, and on May 14, 1970, the court handed down its opinion affirming the July 8, 1968 Order of the Food and Drug Administration. Judge Stahl did not participate in the decision, which occurred after his

death.* A Petition for Rehearing was filed both by petitioner and the Corn Products Company. The court denied the respective Petitions for Rehearing on June 22, 1970.

REASONS FOR GRANTING WRIT

Whether, under the Administrative Procedure Act, 5 U.S.C. § 577(c)(A), the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §371(e)(3), and the decisions of this Court, it is required, in a rule making proceeding directed by statute to be made on the record after an opportunity for a hearing, that the Food and Drug Administration set forth findings of fact which provide reasons or basis supporting its rejection of a fundamental and material issue of fact raised by objections and by the evidence of record presented at the hearing?

Petitioner respectfully asserts that the resolution by the Court of this question of federal administrative law is essential in order to protect the statutory rights of petitioner, to delineate appropriate standards with respect to the administration of the Federal Food, Drug, and Cosmetic Act, and to preserve the integrity of the administrative process.

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* In *Ayrshire Collieries Corp.* v. *United States*, 331 U.S. 132, 139 (1947), this Court made the following observations:

> Moreover, we cannot say that the failure of the third judge to participate in the determination of a case, where the other two are in agreement as to the result, is without significance. The decision reached by two judges is not necessarily the one which might have been reached had they had the benefit of the views and conclusions of the third judge. And should the latter have publicly indicated an opinion differing from that of his colleagues, his position might be helpful to the litigants and to this Court if the case were appealed.

Although *Ayrshire* is distinguishable from the subject case in that the operative law therein specifically called for a three judge court and made no provisions for a quorum of less than three judges (*Cf.* 28 U.S.C. §46(d)), the Court's observations in *Ayrshire*, are pertinent to the situation presented in this case.

Section 701(e) of the Act, 21 U.S.C. §371(e), in pertinent part, provides that any person who will be adversely affected by an order of the Secretary promulgated pursuant to Section 401 of the Act, 21 U.S.C. §341, may file objections and request a public hearing upon such objections, and that

> [T]he Secretary, after due notice, shall hold such a public hearing, for the purpose of receiving evidence relevant and material to the issues raised by such objections. . . . As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based.

Section 8(b) of the Administrative Procedure Act (APA), 5 U.S.C. §557(c)(A), in pertinent part, provides that where, as is the case here, rules are required by statute to be made on the record after opportunity for an agency hearing, all decisions "shall include a statement of—(A) findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the record."*

Although the Court of Appeals in a footnote stated that "we are not prepared to state that in an appropriate situation specific findings could not be required," it concluded that in the subject case the Commissioner's recognition in the preamble to the Order that petitioner would be adversely affected by the Order is "sufficient

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* The applicability of the provisions of the Administrative Procedure Act to administrative matters under the Federal Food, Drug, and Cosmetic Act was made clear by this Court's decision in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967). *Also see* 5 U.S.C. §559 and 21 U.S.C. §371(e)(6).

specificity," *Derby Foods, Inc., supra*, at p. 517. We respectfully disagree with the conclusion of the court as it relates to the "sufficient specificity" of the resolution of the objections of petitioner Derby. There is a basic distinction between a statement recognizing a fundamental and material issue of fact raised in the objections and in the evidence of record, and one providing "reasons or basis" as to why the evidence in support of the objections was not considered controlling. Not only is it the clear mandate of Section 8(b) of the APA and Section 701(e) of the Act that "reasons or basis" be provided, but this Court on several occasions has emphasized that "the orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained." *Securities Exchange Commission* v. *Chenery Corporation*, 318 U.S. 80, 94 (1943), *Federal Power Commission* v. *United Gas Pipe Line Co.*, 393 U.S. 71 (1968), *Colorado-Wyoming Gas Co.* v. *Federal Power Commission*, 324 U.S. 626 (1945). "The administrative process will best be vindicated by clarity in its exercise." *Phelps Dodge Corp.* v. *National Labor Relations Board*, 313 U.S. 177, 197 (1941). Section 8(b) of the APA, Section 701(e) of the Act, and the decisions of this Court, require the conclusion that this is "an appropriate situation" for specific reasoned findings.

In *Burlington Truck Lines, Inc.* v. *United States*, 371 U.S. 156 (1962), this Court set aside an order of the Interstate Commerce Commission granting a certificate of public convenience and necessity, and remanded the case to the Commission for further proceedings consistent with its opinion. This decision was in part premised upon the Court's determination that the Commission, in promulgating its order, had vio-

lated the specific requirements of Section 8(b) of the APA:*

> There are no findings and no analysis here to justify the choice made, no indication of the basis on which the Commission exercised its expert discretion. We are not prepared to and the Administrative Procedure Act [citing Section 8(b) by way of footnote] will not permit us to accept such adjudicatory practice. *Burlington, supra,* at p. 167.

The Court went on to state:

> The agency must make findings that support its decision, and those findings must be supported by substantial evidence [citations omitted]. Here the Commission made no findings specifically directed to the choice between two vastly different remedies with vastly different consequences to the carriers and the public. Nor did it articulate any rational connection between the facts found and the choice made. *Burlington, supra,* at p. 168.

This rational applies with equal force to the factual setting presented in this case for, like the Interstate Commerce Commission in *Burlington,* the Food and Drug Administration in the subject proceeding has failed to provide the participants, the public, or the courts with any findings or analysis which would justify excluding petitioner's consumer-preferred 87% peanut formulation from the standard established by the Order. Neither the preamble nor the findings specify to any degree reasons or bases why the continued

* Although the administrative proceeding in *Burlington* was designated adjudicatory, Section 8(b) of the APA (5 U.S.C. §557(c)(A)) is equally applicable to rule making proceedings where, as is the situation here, the rules are required by statute to be made on the record after an opportunity for a hearing. *See,* 21 U.S.C. §371(e) and 5 U.S.C. §553(c).

availability of petitioner's formulation is not in the consumers' interest and reasonable (21 U.S.C. §341) or why a standard which would encompass this formulation, as well as those which fall within the Agency's existing order, is not preferable to the one promulgated.

The Court of Appeals, in its opinion, concluded that the Commissioner's findings with respect to a widespread lack of information among consumers concerning the actual composition of peanut butter, a trend by some manufacturers to reduce the peanut content of peanut butter, competitive pressures to substitute "cheaper" optional ingredients for peanuts, and the fact that some State officials have indicated need for a peanut butter standard, "are supported by sufficient rational probative evidence to afford sound basis for the exercise of the Commissioner's judgment to promulgate a standard of identity." *Derby Foods, Inc., supra*, at p. 514. Even assuming that this conclusion of the Court of Appeals is supported by substantial evidence of record, it merely indicates that it would be reasonable to promulgate a peanut butter standard. It does not address itself to the proposition that the standard promulgated is reasonable or that it is supported by substantial evidence of record. In the absence of findings, supported by substantial evidence of record, justifying the exclusion from the standard of identity of peanut butter formulations containing 87% peanuts, and in light of the uncontradicted evidence of record that the 87% "peanut" formulations of petitioner and Corn Products Company are preferred by vast numbers of consumers and possess all of the essential attributes of peanut butter, the standard as established by the Order simply cannot be sustained. This is especially so due to the fact

that a reasonable standard could have been promulgated which would encompass these two leading formulations and at the same time effectively terminate whatever trend there might be to increase unnecessarily the optional ingredient content of peanut butter.* This is not a situation where a choice of two mutually exclusive alternatives exists, each reasonable in its own right. Rather, this is a situation where the adoption of the promulgated standard has the consequence of denying to consumers, without providing any justification, the continued availability of peanut butter formulations for which consumers have demonstrated a preference and which, by every meaningful parameter, are no less than the equivalent to any peanut butter coming within the promulgated standard.

In addition, it is important to note that although the standard established by the Order would prohibit, without justification, the continued availability of petitioner's formulation containing 87% "peanuts," it would permit, as recognized by the Court of Appeals, *Derby Foods, Inc., supra* at p. 516, the marketing of peanut butter formulations containing as little as 68% "peanuts." No findings were made which would permit such an obvious and disturbing incongruity.

In *Baltimore & Ohio Railroad Co.* v. *Aberdeen & Rockfish Railroad Co.*, 393 U.S. 87 (1968), this Court affirmed, with modifications not pertinent herein, a decision of a three-judge district court, 270 F. Supp. 695 (E.D. La. 1967), setting aside and remanding for further proceedings an order of the Interstate Com-

* If the standard of identity for peanut butter were to establish a peanut floor at 87%, no manufacturer could market a "peanut butter" in interstate commerce which contained less than that amount of peanuts. See, 21 U.S.C. §343(g) and 21 U.S.C. §331(a) and (b).

merce Commission prescribing "just, reasonable and equitable divisions" of joint rates, promulgated pursuant to Section 15(6) of the Interstate Commerce Act, 24 Stat. 384. The district court held that the Commission's order was not supported by substantial evidence and reasoned findings within the meaning of Section 8(b) and 10(e) of the APA. In its decision, this Court concluded that the Commission's assertion that the "territorial average costs were 'adjusted' to reflect the costs attributable to the North-South traffic issue" must be supported by "specific findings . . . on the several items of so-called 'adjustment' of average territorial costs." *Baltimore & Ohio R.R. Co., supra*, at p. 93. In so ruling, the Court stated:

> We agree with the District Court that there is no substantial evidence that territorial average costs are necessarily the same as the comparative costs incurred in handling North-South freight traffic. If we were to reverse the District Court, we would in effect be saying that the expertise of the Commission is so great that when it says that average territorial costs fairly represent the costs of North-South traffic, the controversy is at an end, even though the record does not reveal what the nature of that North-South traffic is. The requirement for administrative decisions based on substantial evidence and reasoned findings—which alone make effective judicial review possible—would become lost in the haze of so-called expertise. Administrative expertise would then be on its way to becoming "a monster which rules with no practical limits on its discretion." *Burlington Truck Lines v. United States*, 371 U.S. 156, 167. That is impermissible under the Administrative Procedure Act. *Baltimore & Ohio R.R. Co., supra*, at pp. 91, 92.

Likewise, in the subject case, the Agency's failure to provide reasoned "specific findings" with respect to

why the evidence as to the unreasonableness of the Order in not allowing "peanut butter" to contain 13% optional ingredients was not considered controlling, is "impermissible under the Administrative Procedure Act." The Agency's recognition of this material issue of fact presented on the record does not resolve the issue nor does it satisfy the fundamental requirements of the APA as enunciated by this Court.

In the hands of the Commissioner of the Food and Drug Administration rests the triple role of proposing rules and orders which affect fundamental property and personal rights, of presenting evidence on such proposed rules and orders, and of resolving the issues raised by such proposals. He acts as proposer, advocate and judge. This immense power presents a potential for abuse which can be minimized by requiring the Commissioner to set forth for public scrutiny specific findings specifying his reasons or basis for resolving fundamental and material issues raised by his proposals. The integrity of the adminitrative process is dependent upon observance of such a procedure. The APA, the Act, and the decisions of this Court, require that such procedure be followed. The Commissioner can do no less and petitioner seeks no more.

CONCLUSION

For the reason stated above, it is respectfully requested that a Writ of Certiorari be granted in this case.

Respectfully submitted,

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September 18, 1970

APPENDIX A

Statutory Provisions

The Administrative Procedure Act:

5 U.S.C. § 553(c). Rule making

> ". . . When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

5 U.S.C. § 557(c)(A). Initial decisions; conclusiveness; review by agency, submissions by parties, contents of decisions, record

> ". . . The record shall show the ruling on each finding, conclusion, or exception presented. All decisions, including initial, recommended, and tentative decisions are a part of the record and shall include a statement of—(A) findings and conclusions, and the reasons or basis therefore, on all the material issues of fact, law, or discretion presented on the record; and"

5 U.S.C. § 559. Effect on the other laws; effect of subsequent statute

> "This subchapter, chapter 7, and sections 1305, 3105, 3344, 4301(2) (E) 5362, and 7521 of this title, and the provisions of section 5335 (a)(B) of this title that relate to hearing examingrs, do not limit or repeal additional requirements imposed by statute or otherwise recognized by law. Except as otherwise required by law, requirements or privileges relating to evidence or procedure apply equally to agencies and persons. Each agency is granted the authority necessary to comply with the requirements of this subchapter through the issuance of rules or otherwise. Subsequent statute

may not be held to supersede or modify this subchapter, chapter 7, sections 1305, 3105, 3344, 4301 (2)(E), 5362, or 7521 of this title, or the provisions of section 5335(a)(B) of this title that relate to hearing examiners, except to the extent that it does so expressly."

The Federal Food, Drug, and Cosmetic Act:

21 U.S.C. § 331 (a) and (b). Prohibited Acts

"The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce."

21 U.S.C. § 341. Definitions and Standards for Foods

"Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: Provided, that no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the

prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing."

21 U.S.C. §343(g). Misbranded Food

"A food shall be deemed to be misbranded . . . (g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring and coloring) present in such food."

21 U.S.C. §371 (e) and (f). Regulations and Hearings

"(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502(d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary

shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by

order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary,

and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence, so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive [now covered by U.S.C. title 28, sec. 1254].

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

APPENDIX B

(Reprinted from the Federal Register of July 24, 1968; 33 F.R. 10506)

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

[Docket No. FDC-76]

PART 46—NUT PRODUCTS

Peanut Butter, Definition and Standard of Identity; Findings of Fact, Conclusions, and Final Order

In the matter of establishing a definition and standard of identity for peanut butter:

A notice of proposed rulemaking was published in the FEDERAL REGISTER of July 2, 1959 (24 F.R. 5391), setting forth a proposal by the Commissioner of Food and Drugs to establish a definition and standard of identity for peanut butter. Based upon views and comments received and other information available at that time, the Commissioner published in the FEDERAL REGISTER of November 28, 1961 (26 F.R. 11209), an order establishing a definition and standard of identity for this food. Thereafter, objections were filed in accordance with the provisions of section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act, and the Commissioner published an order in the FEDERAL REGISTER of February 1, 1962 (27 F.R. 943), staying the effective date of the standard in its entirety. Subsequently, additional information was received, and the Commissioner published a proposed revision of the identity standard for peanut butter in the FEDERAL REGISTER of November 10, 1964 (29 F.R. 15173), and solicted the views and comments of all interested persons on that revision. Many comments were filed by interested persons—manufacturers of peanut butter, in-

gredient suppliers, cooperative associations, regulatory officials, nutritionists, consumer associations, and individual consumers.

Based upon the comments received and other relevant information, the Commissioner again published an order in the FEDERAL REGISTER of July 8, 1965 (30 F.R. 8626), establishing a definition and standard of identity for peanut butter. Objections were filed in accordance with the provisions of section 701(e)(2) of the act and a public hearing was requested. The Commissioner published an order in the FEDERAL REGISTER of September 4, 1965 (30 F.R. 11349), staying the effective date of the standard in its entirety pending a resolution of the issues at a public hearing.

In the FEDERAL REGISTER of September 18, 1965 (30 F.R. 11970), the Commission published a notice announcing a public hearing to begin October 18, 1965, for the purpose of receiving evidence relevant and material to the issues set forth in that notice, and also announcing a prehearing conference to begin October 4, 1965, for certain specified purposes. A notice rescheduling the date of the hearing and announcing a second prehearing conference was published in the FEDERAL REGISTER of October 12, 1965 (30 F.R. 12949). The second prehearing conference was to begin on October 20, 1965, and was completed on that date. As rescheduled, the public hearing began on November 1, 1965, and the taking of testimony concluded on March 15, 1966.

Based upon the evidence received at the hearing and consideration given to written arguments and suggested findings, the Commissioner published proposed findings of fact, conclusions, and tentative order in the FEDERAL REGISTER of December 6, 1967 (32 F.R. 17482), and invited exceptions thereto.

The sponsors of the two leading brands of peanut butter argue for the 87-percent peanut requirement for two quite different reasons, each of which is said to be essential to the consumer's acceptance of its product. The manufacturer

of Skippy brand states that approximately 8½ percent of hydrogenated oil is necessary to make its product acceptable, and the manufacturer of Peter Pan brand states that approximately 9 percent of dextrose is essential for its particular consumer appeal.

The record is clear that the desired emulsification and the properties desired by consumers, such as spreadability and freedom from stickiness, can be obtained by a 3 percent of hydrogenated oil or a higher percentage if lightly hydrogenated oil is used. Since commercial processes used in producing hydrogenated peanut oil destroy peanut flavor and make peanut oil the same bland material as other hydrogenated oils, there is no advantage to the consumer in the use of higher than needed hydrogenated oil for emulsification and stability. While Skippy brand peanut butter has gained acceptance in the marketplace, allowance of 13 percent of nonpeanut materials would open the way for excessive use of these materials and consequent abuse of the consumer's interest.

Peter Pan brand peanut butter has gained acceptance in the market. Indeed, the evidence shows that in the opinion of Swift and Co., the parent manufacturing firm, it was better than Skippy brand when it had 5 percent dextrose, 3 percent stabilizer, and 1.7 percent salt. Only by increasing the dextrose an additional 4 percent at the expense of peanuts did the manufacturer of Peter Pan brand "uniquely improve" the product.

Peanut butter should, in the consumer's interest, consist of ground peanuts and the level of optional ingredients necessary to serve technological purposes. About 1 to 2 percent salt is all that is customarily employed. Within 8 to 9 percent any number of combinations of emulsifiers and sweetening agents can be employed; for example, 5 percent of sweetner and 3 percent of emulsifier have been found to be quite satisfactory. The 90-percent level of peanuts in peanut butter is attainable in good manufacturing prac-

tice, is being met by many producers, insures a reasonable level of peanut content, and allows for modification of the product to have properties consumers desire such as spreadability, stability, freedom from stickiness, etc., without excess of foreign and cheapening ingredients.

There is nothing in the final order that outlaws Skippy brand peanut butter, Peter Pan brand peanut butter, or any other brand of peanut butter. What is required is that those products that have contained less than 90 percent peanuts henceforth contain more peanuts per pound of peanut butter.

Having considered all the exceptions and written arguments received, and pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055, as amended 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 341, 371) and delegated to him (21 CFR 2.120), the Commissioner issues the following findings of fact, conclusions, and final order:

Findings of fact.[1] 1. Standards of identity are intended to establish or define what a food product is and what a consumer expects to receive when he selects the food by its common or usual name. (R. 2965, 2966; Ex. 51)

2. Peanut butter in the past has been identified in the public mind as an article made essentially from ground peanuts and seasoning. In 1959 the Food and Drug Administration became aware of a trend by some manufacturers to reduce the peanut content of peanut butter. Three surveys conducted by the Food and Drug Administration in 1960, 1963, and 1965 confirmed this trend. The changes in formulation that resulted in a decrease of peanuts in peanut butter were not always intended for the benefit of the

[1] The citations following each finding of fact refer to the pages of the transcript of testimony and the exhibits received in evidence at the hearing.

consumer, nor was the consumer made aware of the extent of these changes. (R. 674, 692, 693, 785, 786, 808, 854, 1733, 1919-1921, 2042, 2044, 2048, 2049, 2050; Ex. 14, 14A, 39, 39D, 40, 40A)

3. There is a widespread lack of information among consumers concerning the actual composition of peanut butter. Many consumers and consumer groups have stated that there is a need for a standard of identity for peanut butter. Other consumers believe that a standard has already been established and is in effect. (R. 738, 739, 2394, 4724, 4725, 4751, 6170; Ex. 11A, 22B, 106, 118)

4. State food and drug agencies have received complaints concerning additives used in peanut butter, and the State officials have indicated need for a peanut butter standard. If a Federal definition and standard of identity is not promulgated, these officials will seriously consider recommending the adoption of individual State standards of identity for peanut butter. (R. 743, 746, 748, 749, 751, 1231, 1233)

5. In 1959 the Peanut Butter Manufacturers Association adopted a position opposing a standard in any form. Certain manufacturers of peanut butter, including some who are members of the Association, do not support the position of the Association and express the opinion that a definition and standard of identity for peanut butter is needed. (R. 1175, 1590, 1670, 1813, 1816, 1817, 1826, 1828, 1854, 1858, 1918, 1919, 2011, 2014, 2020, 2025, 2044, 2048, 2164, 2581, 3123, 3295, 5919; Ex. 10A, 10B, 10C, 40, 41, 83)

6. The manufacture of peanut butter dates back at least to 1890. It has commonly been made from peanuts, salt, and, sometimes, sugar. Peanut butter so made, sometimes referred to as "old-fashioned" peanut butter, was as recently as 1941 the predominant type sold. "Old-fashioned" peanut butter had the disadvantages of oil separation, difficulty in remixing, stickiness, graininess, lack of spreadability, development of rancidity, and short shelf-life. It was usually

made by numerous manufacturers for relatively local distribution. (R. 342, 4097, 4098, 4101, 4393, 4094, 4898, 4899)

7. Research and development affecting the characteristics of peanut butter have been aimed at preventing separation of oil, eliminating stickiness, increasing spreadibility, and achieving stability against temperature changes and shocks in transportation. From 1921 onward there is record of the introduction of various stabilizing and seasoning ingredients of peanut butter. These included hydrogenated oils, solid fats or oils, mono- and diglycerides, lecithin, sugar, dextrose, corn syrup, and honey. Such changes in formulation were sometimes accompanied by changes in machinery and manufacturing techniques. These developments have made it possible to distribute peanut butter nationally instead of just locally. (R. 342-47, 405, 2175, 2176, 3181, 3440, 4266, 4395, 4900, 4916; Ex. 28, 29, 30, 75, 98, 99A, 99B)

8. Some optional ingredients are used in place of peanuts to make a more acceptable product for the benefit of consumers or because they are cheaper than peanuts and their use would allow the manufacturer a competitive advantage in the market or both. (R. 1018, 1019, 1175, 1479, 1498, 1499, 1503, 1518, 1677, 1678, 1718, 1817, 1826, 1835, 1836, 2025, 2048, 2050, 2165, 2582-2584, 3203, 3514, 3975, 4125, 4422, 5445, 5919; Ex. 14, 14A 40, 40A)

9. At the present time, stabilized peanut butter has largely displaced unstabilized or old-fashioned peanut butter in the market place. The sale of stabilized peanut butter is increasing faster than that of unstabilized. (R. 382, 1706, 3183, 3185, 3444, 3453; Ex. 14, 39, 40)

10. Industry practices by both large and small manufacturers should be considered in promulgating a standard of identity, but a definition and standard of identity need not embrace all existing industry practices. (R. 848, 2191, 2628)

11. Some manufacturers do not consider the stayed standard of July 8, 1965, reasonable because it does not encompass their products which employ more than 10 percent total optional ingredients. (R. 3189, 3448, 3613, 5412)

12. In surveys conducted by the Food and Drug Administration in 1963 and 1965, it was found that a majority of the manufacturers from whom data were obtained produced only peanut butter containing 90 percent or more of peanuts and that others were making part of their production in this range. (R. 1160, 1171-72; Ex. 14, 40)

13. Some manufacturers changed their formulations and began using more than 10 percent optional ingredients after the Peanut Butter Manufacturers Association took a position that if a standard is established it should permit 13 percent optional ingredients. (R. 3684-3690; Ex. 14, 39, 40)

14. Many manufacturers that have produced or are producing peanut butter containing 87 percent or less of peanuts have in the past produced or are presently producing hundreds of millions of pounds of peanut butter containing 90 percent or more of peanuts. (R. 438, 3439, 3442, 3659, 4897, 4988, 5457, 5563, 5916, 5917; Ex. 14, 39, 40)

15. Some manufacturers produce peanut butter containing more than 10 percent optional ingredients, the excess being largely due to use of large amounts of a sweetening ingredient lower in sweetening potency than other suitable sweetening ingredients. (R. 3181, 5410; Ex. 14, 39, 40)

16. Sweetening ingredients commonly used in peanut butter are sucrose, dextrose, corn syrup, corn syrup solids, maltodextrins, and honey. Sweeteners differ in sweetening strength; sucrose, dextrose, corn syrup, and maltodextrins differ in sweetness in that descending order. Amounts of dextrose or corn syrup that have been used range up to 9 percent of the finished peanut butter and maltodextrins have been used in amounts as great as 14 percent. Surveys conducted by the Food and Drug Administration in 1963

and 1965 showed that some peanut butter manufacturers had changed to larger amounts of sweetener than they had previously used and thereby reduced the peanut content of their products. In some cases a sweetener was replaced with a larger amount of a less potent sweetener. (R. 342-47, 1479, 1817, 2021, 2026, 2047, 3181, 3182, 5406; Ex. 14, 40)

17. Some manufacturers who now use a large percent of sweetening ingredient have in the past produced a satisfactory peanut butter containing 90 percent or more of peanuts by using a smaller amount of a sweetener of greater sweetening strength. This was produced using the same equipment now in use and the product so made would have been in compliance with the stayed standard of July 8, 1965. (R. 3199, 3200, 3635, 3664, 3702, 3703, 3710, 5405, 5457, 5492, 5498, 5499; Ex. 14, 39, 40)

18. Some manufacturers produce peanut butter containing more than 10 percent optional ingredients the excess being largely due to the percentage of hydrogenated oil stabilizer used. (R. 438, 2013, 3436, 4279; Ex. 14, 39, 40)

19. In 1962 the oil content of ground roasted peanuts used for manufacture of peanut butter was found by a manufacturer to range in the case of Runner variety from 49 to 55 percent; in the case of Spanish variety from 45 to 56 percent; and in the case of Virginia variety from 45 to 52 percent. A survey conducted by the Food and Drug Administration in 1960 yielded results closely similar to these. (R. 3758, 3759; Ex. 19)

20. Removal of oil from the peanut ingredient is something practiced in the manufacture of peanut butter, and this removal of oil is said to be needed with extremely oily peanuts. (R. 495, 899-900, 1321, 2080, 2166, 2584, 3082; Ex. 7)

21. The stayed standard of July 8, 1965, set a limit of not more than 55 percent total fat in the finished peanut butter because this was deemed sufficient to provide for peanut butter that might be made from peanuts naturally high in oil, even with no other ingredient. (R. 3082; Ex. 7)

22. Some manufacturers have added unhydrogenated peanut oil or other unhydrogenated vegetable oils to compensate for deficiency in oil content of the peanut ingredient. Addition of oil is needed only with peanuts that are characteristically low in oil content. Oils other than peanut oil are foreign to the peanut ingredient, and only peanut oil is suitable for this adjustment. (R. 495, 899-900, 1321, 1671, 1680, 1754, 2050, 2080, 2166, 2584, 3196, 5020, 5970, 5974-75; Ex. 7, 14, 40)

23. The amount of stabilizer needed relates primarily to the amount of free oil in the peanut butter system whether that free oil is from the peanuts or is added peanut oil. Peanut butter made from peanuts with a high oil content might require more stabilizer than that made from peanuts of lower oil content, depending on the characteristics desired by the manufacturer. (R. 2615, 2616, 5143)

24. Hydrogenated vegetable oils differ physically from their source oils. In proportion to the degree of hydrogenation, they are less fluid at ordinary temperatures and have higher melting points than their source oils. Partially and fully hydrogenated oils range in form from white plastic substances to white solids which may in some cases be hard enough to be flaked or granulated. (R. 2645, 2646, 4935)

25. Hydrogenated vegetable oils differ chemically in a number of respects from their source oils. Hydrogenated oils contain a higher percentage of saturated fatty acids and a lower percentage of unsaturated fatty acids than their source oils the amount of difference depending on the extent of hydrogenation. Hydrogenation also changes some of the minor constituents occurring in the unsaponifiable fractions of certain oils. (R. 2646, 2648, 4935, 4936)

26. One of the more widely sold brands of peanut butter contains less than 10 percent total optional ingredients, but does not conform to the stayed standard of July 8, 1965,

because it contains more than 3 percent of a blend of partially hydrogenated oils of nonpeanut origin. With respect to this product there was testimony that 3 percent of a more fully hydrogenated stabilizer would prevent oil separation but would not give the other desired characteristics in this product such as stability and absence of a waxy feel in the mouth. (R. 4909, 4910, 4920, 4927, 5134)

27. It was testified that a limitation of not over 3 percent of hydrogenated vegetable oils other than hydrogenated peanut oil in peanut butter is unnecessary. Products having a preferred combination of properties (stability against oil separation and against change in consistency with temperature; spreadability and freedom from stickiness) were asserted to require the use of partially hydrogenated oils or oils hydrogenated to various degrees, other than hydrogenated peanut oil, in amounts more than 3 percent but not more than 10 percent of the food. Hydrogenated and partially hydrogenated oils such as cottonseed oil are used as source oils for the manufacture of mono- and diglycerides which, under the stayed standard of July 8, 1965, may be used in any amount up to the limit for total optional ingredients; namely, 10 percent of the food. (R. 2640, 3436, 3447, 4910, 4920, 4927, 4928, 4937, 5134, 5149).

28. Hydrogenated vegetable oils used as stabilizing ingredients in peanut butter are decolorized and deodorized after hydrogenation and are substantially free from any characteristic flavor. Such refining also reduces the content of unsaponifiable matter. Peanut butter made with a stabilizer derived from peanut oil does not have a flavor different from one made with the same amount of a stabilizer derived from nonpeanut oil sources. (R. 2685, 4941)

29. Hydrogenation of vegetable oils changes their identity so that they can no longer be considered the respective source oils. They may retain many of their original properties but they are not the same. (R. 391, 408, 409, 413, 418, 521, 1303, 2646)

30. The medical literature does not show that fats and oils are generally considered by allergists as foods likely to cause allergic responses. (R. 7466)

31. The various hydrogenated vegetable oils used as stabilizing ingredients in peanut butter are alike in nutritional value. From the nutritional standpoint there is no need to specify on labels the source of a hydrogenated oil in peanut butter. (R. 4023, 4024, 4032, 5601)

32. Hydrogenated vegetable oils used in peanut butter stabilizers are so changed in physical and chemical characteristics from the source oils that it is appropriate to designate them as "hydrogenated (or hardened) vegetable oils" rather than to identify the source oils. In composition and physical attributes they resemble each other more closely than they do their respective source oils. (R. 4934-37)

33. Sucrose is purified by recrystallization and is identical whether produced from cane or beets. No need has been shown for requiring its source to be shown on labels of peanut butter. (R. 2251-52)

34. Stabilizing ingredients used in peanut butter include hydrogenated or partially hydrogenated peanut oil, hydrogenated or partially hydrogenated vegetable oils other than peanut oil, mono- and diglycerides, glyceryl monostearate, lecithin, and hydroxylated lecithin. (R. 363, 405, 716, 1172, 1173, 2652, 3164, 4909, 5145; Ex. 14, 40)

35. Lecithin and hydroxylated lecithin are safe and suitable stabilizing ingredients for peanut butter. (R. 725, 3164, 5145; Ex. 7)

36. The stabilizing ingredient known as mono- and diglycerides is a safe and suitable stabilizing ingredient for peanut butter. It is made by reacting fats or fatty acids with glycerin. It may be made from any fat or oil, including partially and fully hydrogenated fats and oils. A typical product contains about 10 percent of unreacted

triglycerides, the remainder consisting of approximately equal amounts of monoglycerides and diglycerides. Mono- and diglycerides are effective stabilizing ingredients for peanut butter when used in limited amounts; if too much is used the food sets up too hard. The common name of this ingredient and the name by which it should be designated on the label of peanut butter is "mono- and diglycerides." (R. 839, 2282, 2748-49, 2785, 2928, 4927, 5176; Ex. 7)

37. The stabilizing ingredient glyceryl monostearate, or monoglycerides, is a commercial product distinct from that known as mono- and diglycerides, though chemically it belongs to the same class. Technically, it is used in the same way and is subject to the same limitations on amount used (see finding 36). It is obtained by distillation from mono- and diglycerides and commonly contains at least 90 percent of monoglycerides of saturated fatty acids, mainly stearic and palmitic. Monoglycerides of this degree or purity when used as ingredients of peanut butter are appropriately designated on the label as "glyceryl monostearate" or as "monoglycerides." (R. 2529, 2785-86, 2928, 5193-94; Ex. 73, 74, 127A, 127B)

38. Synthetic glycerin meeting U.S.P. specifications is suitable for manufacture of mono- and diglycerides used as ingredients of peanut butter. (R. 2731, 6754; Ex. 130A, 130B)

39. The tocopherols naturally present in peanuts have an antioxidant effect. (R. 2653, 2783)

40. It would not be in the interest of consumers to provide for addition of artificial sweeteners to a high calorie food such as peanut butter. The use of artificial sweeteners to replace nutritive sweeteners in peanut butter would actually increase its caloric content and lead to consumer deception. (R. 1101, 3957)

41. Artificial color could be used to conceal inferiority in peanut butter. (R. 1318, 5905)

42. A peanut butter product containing artificial flavor is not peanut butter. Peanut butter has a distinctive flavor of its own and there is no reason to alter its flavor by the addition of artificial flavoring. Artificial flavoring can be used to conceal inferiority in peanut butter. (R. 1098, 1675, 2627, 2628, 5904, 5905, 6123)

43. Three government agencies—Department of Agriculture, Veterans' Administration, and Department of Defense—purchase approximately 47 million pounds of peanut butter a year and, except for the small amount purchased by the Department of Defense for combat rations, do not call for fortification of the peanut butter with vitamins because they conclude there is no nutritional justification for it. The Food and Nutrition Board of the National Research Council in April of 1962 unanimously decided not to endorse the addition of vitamins to peanut butter. (R. 626, 922, 960, 1961, 1962, 2227, 2228, 2232; Ex. 12, 13, 16)

44. It is not the practice of peanut butter manufacturers to add antioxidants, artificial flavors, artificial sweeteners, chemical preservatives, or color additives to peanut butter, nor is there any need, nutritional or other, for the addition of these substances. (R. 605-607, 632-634, 1101, 1102, 1107, 1108, 1112, 1128, 1675, 2078, 2079, 2163, 2164, 2579, 2653, 3514, 3702, 4060, 4238, 4358, 4359, 5516, 5517, 5619, 5634, 5635, 5636, 5904, 5905; Ex. 14, 15, 16, 39, 40, 73, 74)

45. Wheat germ has been used as a seasoning ingredient in peanut butter in amounts up to 5 percent of the finished food and is a safe and suitable seasoning ingredient for peanut butter. (R. 2081, 2082, 6313, 6331; Ex. 125)

46. Confectionary items containing ground roasted peanuts cannot be made successfully from peanut butter suitable as a household spread. Such peanut butter does not have the consistency required for the manufacture and handling of such confections. (R. 3891, 3913, 6774, 6789, 6809)

47. A consumer buying a confection containing ground peanuts with other ingredients knows he is buying a confection and does not expect it to have the characteristics or identity of the spread known as peanut butter. (R. 3892-94, 3924)

48. The standard of identity for peanut butter should not be applicable to confections that can be readily distinguished by consumers from the article named in the standard. (R. 2083, 2569, 3894, 6810)

49. A product containing 75 percent ground roasted peanuts was for about 3 years, ending in 1961, manufactured and sold as "peanut spread." Thereafter its formulation was changed so that it contained over 90 percent peanuts and it was sold as peanut butter. There was testimony that products containing less peanuts than are prescribed by a standard for peanut butter should be designated by another name such as "peanut spread." There was also testimony that standards for peanut products closely resembling each other, under different names, would cause confusion and not be in the consumer's interest. In the testimony favoring a standard for a product other than peanut butter, various levels of peanut content were proposed but there was no testimony on other requirements of such a standard. (R. 456-57, 582, 597, 1314, 1676, 2089, 2189, 2190, 2542, 2584, 2626, 3128, 3485; Ex. 5, 11A, 49, 64)

50. Ingredients used in peanut butter must not only be safe but also must conform to consumer understanding of the product and be suitable to promote honesty and fair dealing in the interest of consumers. To be suitable, an ingredient must perform a useful function and not cause deception. (R. 566-67, 575, 1073, 1074, 1331)

51. The only optional ingredients for peanut butter that have been shown to perform a useful function and maintain the integrity of the food are seasoning and stabilizing ingredients. (R. 1071-76; Ex. 14, 39, 40)

Conclusions. On the basis of the foregoing findings of fact and giving consideration to the weight of substantial evidence of the entire record, the following conclusions are drawn:

1. The promulgation of a reasonable definition and standard of identity for peanut butter at this time will promote honesty and fair dealing in the interest of consumers.

2. The definition and standard of identity, § 46.1, as established by the order published in the FEDERAL REGISTER of July 8, 1965 (30 F.R. 8626), and stayed by order of the Commissioner of Food and Drugs published September 4, 1965 (30 F.R. 11349), will be reasonable and will promote honesty and fair dealing in the interest of consumers if it is amended to:

a. Remove the limitation in § 46.1(c) that not more than 3 percent of hydrogenated oils other than hydrogenated peanut oil may be used as optional stabilizing ingredients in peanut butter.

b. Provide that hydrogenated vegetable oils used as optional stabilizing ingredients for peanut butter may be designated on the label either by the names of their respective vegetable sources or as hydrogenated (or hardened) vegetable oils.

3. It is not necessary in order to promote honesty and fair dealing in the interest of consumers to specify, except as set forth in § 46.1 (c) and (c)(1) as amended in this tentative order, what stabilizing ingredients other than hydrogenated vegetable oils are suitable optional ingredients for peanut butter as performing a useful function in its manufacture, or how they should be designated on the label of this food.

4. It will promote honesty and fair dealing in the interest of consumers for the definition and standard of identity of peanut butter to exclude as optional ingredients each and all of the following substances: Antioxidants;

vitamins A, B_1, C, and D; artificial flavorings; artificial sweeteners; chemical preservatives; and color additives.

5. Partially defatted wheat germ is a safe and suitable seasoning ingredient for peanut butter.

6. It is not necessary to amend the stayed standard for peanut butter to state specifically that it is not applicable to confectionary items that may be composed in part of peanut butter. The peanut components of peanut confections are of necessity different from peanut butter in composition and physical characteristics.

7. There is insufficient evidence of record upon which to promulgate a definition and standard of identity for a food product made from ground peanuts having a lower amount of peanut ingredient than the minimum amount of peanut ingredient contained in peanut butter.

8. It would not promote honesty and fair dealing in the interest of consumers for the definition and standard of identity for peanut butter to provide for the inclusion of any optional ingredients other than seasoning and stabilizing ingredients.

On the basis of the foregoing findings of fact and conclusions drawn therefrom, it is concluded that it is reasonable and will promote honesty and fair dealing in the interest of consumers to establish a definition and standard of identity for peanut butter substantially as set forth in the tentative order of December 6, 1967 (subparagraph (2) of paragraph (e) has been eliminated and the text of subparagraph (1) has been redesignated as paragraph (e)).

Therefore, it is ordered, That the definition and standard of identity for peanut butter be established by revising § 46.1 to read as follows, effective as indicated below:

§ 46.1 Peanut butter; identity; label statement of optional ingredients.

(a) Peanut butter is the food prepared by grinding one of the shelled and roasted peanut ingredients provided for by paragraph (b) of this section, to which may be added safe and suitable seasoning and stabilizing ingredients provided for by paragraph (c) of this section, but such seasoning and stabilizing ingredients do not in the aggregate exceed 10 percent of the weight of the finished food. To the ground peanuts, cut or chopped, shelled, and roasted peanuts may be added. During processing, the oil content of the peanut ingredient may be adjusted by the addition or subtraction of peanut oil. The fat content of the finished foods shall not exceed 55 percent when determined as prescribed in section 25.004 *Crude Fat—Official, First Action*, paragraph (a) *Direct method*, in "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th Edition, page 412.

(b) The peanut ingredients referred to in paragraph (a) of this section are:

(1) Blanched peanuts, in which the germ may or may not be included.

(2) Unblanched peanuts, including the skins and germ.

(c) The seasoning and stabilizing ingredients referred to in paragraph (a) of this section are suitable substances which are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act, or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Seasoning and stabilizing ingredients that perform a useful function are regarded as suitable, except that artificial flavorings, artificial sweeteners, chemical preservatives, added vitamins, and color aditives are not suitable ingredients of peanut butter. Oil products used as optional stabilizing ingredients shall be hydrogen-

ated vegetable oils. For the purposes of this section, hydrogenated vegetable oil shall be considered to include partially hydrogenated vegetable oil.

(d) If peanut butter is prepared from unblanched peanuts as specified in paragraph (b)(2) of this section, the name shall show that fact by some such statement as "prepared from unblanched peanuts (skins left on)." Such statement shall appear prominently and conspicuously and shall be in type of the same style and not less than half of the point size of that used for the words "peanut butter." This statement shall immediately precede or follow the words "peanut butter," without intervening written, printed, or graphic matter.

(e)(1) The label of peanut butter shall name, by their common names, the optional ingredients used, as provided in paragraph (c) of this section. If hydrogenated vegetable oil is used, the label statement of optional ingredients shall include the words "hydrogenated ..... oil" or "hardened ..... oil," the blank being filled in either with the names of the vegetable sources of the oil or, alternatively, with the word "vegetable"; for example, "hydrogenated peanut oil" or "hardened peanut and cottonseed oils" or "hydrogenated vegetable oil."

Effective date. This order shall become effective 90 days from the date of its publication in the FEDERAL REGISTER. (Secs. 401, 701, 52 Stat. 1046, 1055, as amended 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 341, 371)

Dated: July 8, 1968.

WINTON B. RANKIN,
Deputy Commissioner
of Food and Drugs.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 17689

DERBY FOODS, INC., Petitioner

v.

FOOD & DRUG ADMINISTRATION,
U.S. DEPARTMENT OF H.E.W., Respondent

[May 14, 1970]

ON PETITIONS FOR REVIEW OF AN ORDER OF THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

Before STALEY, SEITZ and STAHL,* Circuit Judges

Opinion of the Court

By STALEY, *Circuit Judge*:

Corn Products Company and Derby Foods, Inc.,[1] petition for review of an order of the Food and Drug Administration, Department of Health, Education and Welfare, which establishes a definition and standard of identity for the food product known as peanut butter.[2] They seek

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* Judge Stahl heard the argument and participated in the consideration of this appeal but not in the decision which occurred after his death.

[1] Because of the prior pendency of the petition of Corn Products before this court, Derby Food's petition to the United States Court of Appeals for the Seventh Circuit was transferred here in compliance with 28 U.S.C. §2112.

[2] The standard is set forth at 21 C.F.R. §46.1 (1970).

this review because their products, as they were formulated at the time of the order, fail to conform to the standard.[3]

The order was promulgated under Section 401 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 341.[4] Basically, it limits the percentage by weight of optional ingredients which may be added to the peanut ingredient to a maximum of ten per cent. It allows for the addition or removal of peanut oil and limits the fat content to 55 per cent. The standard also identifies allowable additives and specifies certain labelling requirements.[5]

As originally constituted, peanut butter was composed of ground peanuts, salt, and sometimes sugar. However, this product had the disadvantages of oil separation, stickiness, short shelf-life, etc. These deficiencies have been diminished, if not eliminated, by the addition of stabilizing ingredients, hydrogenated vegetable oils. Today, peanut butter consists of the peanut ingredient, which has a solid component and an oil component, the stabilizer, and seasonings.

Petitioners are the major producers of peanut butter. Each has enjoyed a high degree of success. In 1965 Corn

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[3] Failure to comply with a standard and definition of identity subjects the violator to the penalty provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§331, 333 (1967).

[4] The order was issued under the authority of a deputy commissioner to whom such authority has been delegated. 21 C.F.R. §§2.120, 2.121 (1970).

[5] Procedurally, the statutory requirements have been fulfilled, 21 U.S.C. §371. The initial order issued June 25, 1959, 24 Fed. Reg. 5391 (July 2, 1959). Objections caused a revision, and a second order was published, 26 Fed. Reg. 11209 (Nov. 28, 1961), but its effectiveness was stayed, 27 Fed. Reg. 943 (Feb. 1, 1962). After a proposed revision, 29 Fed. Reg. 15173 (Nov. 10, 1964), and a third order, 30 Fed. Reg. 8626 (July 8, 1965), objections were filed and a public hearing was requested. Notice of the hearing was given, 30 Fed. Reg. 11979 (Sept. 18, 1965), and a hearing was held. The order appealed from issued, 33 Fed. Reg. 10506 (July 24, 1968).

Products, the industry leader, claimed 22 per cent of the market for its brand, Skippy. Derby as the second leading producer had 14 per cent of the market from its product, Peter Pan.[6] Their product formulations fail to qualify under the standard since each uses in excess of ten per cent of optional ingredients as these are defined by the standard, but each for a different reason.

Both petitioners were unsuccessful in urging the Food and Drug Administration to adopt a standard which would allow 13 per cent of optional ingredients, i.e., consist of 87 per cent peanuts. Corn Products urges here that the adoption of the 90 per cent standard was unreasonable and arbitrary and that the standard will not promote honesty and fair dealing in the interest of consumers. It also argues that the findings upon which the order is based are not supported by substantial evidence. Both petitioners contend that they were entitled to specific findings as to why their products were eliminated.[7] Since this is an appeal from an order of an administrative agency, our first concern must be the extent of our authority to review the order.

The scope of review of the appellate court in considering such orders is defined by the Federal Food, Drug and Cosmetic Act and the Administrative Procedure Act. Section 701(f)(3) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 371(f)(3), provides:

> "The findings of the Secretary as to facts, if supported by substantial evidence, shall be conclusive."

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[6] The market percentages quoted are taken from Corn Product's brief and are not indispute.

[7] Corn Products raises an additional issue, asserting a 'taking' of property in violation of the Fifth Amendment. It has been held that wholesome food products may be banned by legislative action. Carolene Products Co. v. United States, 323 U.S. 18 (1944); Hebe Co. v. Shaw, 248 U.S. 297 (1919).

Section 10(e) of the Administrative Procedure Act, 5 U.S.C. § 706, provides:

> "* * * [T]he court shall * * * (2) hold unlawful and set aside agency action, findings, and conclusions found to be * * *
>
> "(E) unsupported by substantial evidence * * *."

The Supreme Court has found the "substantial evidence" test to be the same under the Administrative Procedure Act as under the Taft Hartley Act. Universal Camera Corp. v. NLRB, 340 U.S. 474 (1951). This court has applied the teaching of *Universal Camera* to petitions for review of an order under the Federal Food, Drug, and Cosmetic Act, Cream Wipt Food Products Co. v. Federal Security Administrator, 187 F.2d 789 (C.A. 3, 1951); see also, Atlas Powder Co. v. Ewing, 201 F.2d 347 (C.A. 3, 1952), cert. denied, 345 U.S. 923 (1953).

The Supreme Court has indicated that substantiality must be determined in the light of all that the record relevantly presents; that findings must be set aside when the record clearly precludes the agency's decision from being justified by a fair estimate of the worth of the testimony of witnesses or its informed judgment on matters within its special competence or both; and, that "reviewing courts must be influenced by a feeling that they are not to abdicate the conventional judicial function." Universal Camera Corp. v. NLRB, 340 U.S. at 490.

The Commissioner has concluded that adoption of a standard will promote honesty and fair dealing in the interest of consumers. Support for this conclusion is found in the findings. There is a general lack of information among consumers about the actual composition of peanut butter. It was found that a trend toward a decrease in peanut content has not always been in the interest of consumers. Another finding demonstrates that other ingredients are cheaper and that in some cases the reduced peanut content

has resulted from competitive pressure. It was further found that some consumers and state agencies recognize a need for regulation in this area. These findings are supported by sufficient rational probative evidence to afford a sound basis for the exercise of the Commissioner's judgment to promulgate a standard of identity. See Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218 (1943).

In support of its argument that the adoption of the standard requiring 90 per cent peanuts is arbitrary and unreasonable, Corn Products cites its market success, market history, established trade practices, and urges that the purpose of the Act, to prevent confusion and deception among consumers, would be served by a standard which would allow its product to be sold as it is presently formulated. It is at once apparent that this argument is not aimed at debasing the findings and conclusions upon which the order is based, but is rather an argument in support of a standard which would not require Corn Products to change the composition of Skippy.

The court's function, however, is to review the findings to determine if there is substantial evidence to support them. Because the court must consider the evidence in keeping with the normal judicial function, Universal Camera Corp. v. NLRB, supra, the issue of reasonableness would not appear to be completely beyond judicial reach. However, due regard must be given to the integrity of the administrative function. Given a range of reasonable alternatives, the administrator is given the task of selecting the one which, in his judgment, is most appropriate. In such circumstances, the court must defer to his judgment. Federal Security Administrator v. Quaker Oats Co., supra.

Using an affirmative approach to the order under consideration, the issue becomes whether the findings upon which the 90 per cent standard is based are supported by substantial evidence. Corn Products' argument that the standard should have designated partially hydrogenated

peanut oil as peanut ingredient must be directed at those findings which equate them.

Skippy fails to comply with the standard because it contains 8½ per cent of partially hydrogenated peanut oil and an amount of seasonings which together exceed the ten per cent limit on optional ingredients. No distinction is made in the standard between hydrogenated peanut oil and other hydrogenated vegetable oils.

Nine findings of fact deal directly with hydrogenated oils. These hydrogenated vegetable oils were found to resemble each other more than the oils from which they were derived, although many of the properties of the source oils are retained. Hydrogenation, a process by which unsaturated fats are changed to saturated fats through the addition of hydrogen, causes the physical properties, e.g., melting points, to differ from the source oils. The hydrogenated oils are said to be odorless. Four expert witnesses, all chemists, testified to the dissimilarity between vegetable oil and hydrogenated oil. There was testimony that there is no nutritional variation between these oils. The basic function of the hydrogenated oil, to prevent oil separation in the product, is said to be served regardless of the source oil. The use of hydrogenated peanut oil does not add flavor to the product. From the foregoing, it is quite clear that there is substantial evidence to support a conclusion which makes no distinction between hydrogenated vegetable oils. This conclusion rests upon expert testimony and it is well settled that such testimony is sufficient.[8] Erickson v. Fed-

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[8] Corn Products asserts that evidence concerning the significance of its process of hydrogenation was disregarded by the Commissioner. It elicited testimony from its witnesses that use of its hydrogenated oil resulted in a product with greater flavor accessibility and less waxy taste in the mouth. However, the fact that a theory was not accepted does not mean that the evidence was disregarded, since it is the function of the administrative agency as the trier of fact to access the credibility of witnesses and resolve conflicting evidence. See, e.g., W. J. Dillner Transfer Co. v. United States, 277 F. Supp. 420 (W.D. Pa., 1967).

eral Trade Commission, 272 F.2d 318, 321 (C.A. 7, 1959), cert. denied, 362 U.S. 940 (1960). Also see Federal Security Administrator v. Quaker Oats Co., supra.

The Peter Pan formulation, by using 9.6 per cent dextrose, 1.7 per cent stabilizer, and 1.7 per cent seasoning, exceeds the ten per cent optional ingredient limitation. Finding of Fact No. 16 indicates that sweetening agents of various intensities are available. Amounts of sweeteners used range as high as nine per cent of the more potent sweetners and up to 14 per cent of the least potent. From surveys conducted in 1963 and 1965, it was found that some producers increased the amount of sweetener with the resultant reduction in the amount of peanuts. Testimony of witnesses and surveys support these statements.

It was also found that the use of optional ingredients, while to some extent required for product improvement, was in response to competitive pressure, since peanuts are the most expensive component. By limiting the amount of optional ingredients, the effect of the order is to require the use of a more potent sweetener in smaller amounts in combination with stabilizer and salt. Since the Commissioner may act to prevent economic adulteration of a product, Federal Security Administrator v. Quaker Oats Co., supra, the optional ingredients limitation may be seen as an attempt to prevent such an occurrence.

Other findings relate to the 90 per cent requirement. The surveys conducted in 1963 and 1965 support the finding that a majority of manufacturers produced peanut butter containing 90 per cent of peanuts. Further, it was found that other manufacturers who then would not comply with the standard had in the past produced a 90 per cent peanut product. It is noted that compliance with the standard will not require a change of equipment. Expert testimony indicates that for those presently not in compliance only an alteration of formula is necessary.

Inferentially, petitioners contend that an 87 per cent standard would satisfy the purposes of the Act, and there

may be substantial evidence to support a standard which would allow their products to be marketed as formulated. Assuming without deciding that to be so, this does not militate against the conclusion that the findings are supported by substantial evidence. In addition, it does not compel the conclusion that the choice of the 90 per cent level is arbitrary and unreasonable. It would simply indicate that a reasonable standard could have been established which would not require petitioners to change their formulations. Where equally reasonable alternatives are available, the court must refer to the exercise of administrative discretion.

Perhaps the most troubling of the points raised by petitioners is that there exists within the terms of the standard and definition of identity the means for subverting its intent. It is clear that the intent is to provide a practical maximum of peanut ingredient. The standard provides: "During processing, the oil content of the peanut ingredient may be adjusted by the addition or subtraction of peanut oil. The fat content of the finished foods shall not exceed 55 per cent * * *." Petitioner Corn Products demonstrates that this allows the production of a peanut butter containing only 68 per cent peanuts. This is not disputed, but a government witness stated that such a possibility is more hypothetical than real. Petitioners contend that it is unreasonable to exclude their products, which contain approximately 87 per cent peanuts as defined under the standard, while at the same time including the possibility for making 68 per cent peanut butter.

This provision is based upon findings that some adjustment of the oil content of the peanuts is necessary to account for crop variations. Testimony indicated that the oil contents of peanuts is a variable. A government witness testified that some provision for the addition and removal of oil was necessary and that it would reflect a good commercial practice. Corn Products admits that addi-

tion and removal of peanut oil is an established practice. Should a manufacturer market a 68 per cent product, it is apparent that this would violate the spirit if not the letter of the order. Of course, the order is capable of being modified to meet such an eventuality. Certainly, it could not be asserted that a standard is only reasonable if it provides for every possibility. Such an assertion must fall of its own weight, for language which circumscribes conduct is no match for human ingenuity.

Finally, petitioners contend that they are entitled to specific findings containing reasons for the exclusion of their product formulations. They are unable, however, to cite any direct authority for such a contention. Respondent answers that such findings are not required since this is a rule-making activity.

Specific findings have been made concerning objections of parties opposed to such an order, Willapoint Oysters, Inc. v. Ewing, 174 F.2d 676 (C.A. 9), cert. denied, 338 U.S. 860 (1949). Among the cases relied on by petitioners is A. E. Staley Mfg. Co. v. Secretary of Agriculture, 120 F.2d 258 (C.A. 7, 1941). However, that case does not support their position. There, the court in denying rehearing amended its opinion to delete a requirement that a specific finding be made as to the exclusion of petitioner's product. Instead, it suggested a specific finding and further stated, "Perhaps an explanation as to its disposition of petitioner's evidence would be sufficient," A. E. Staley Mfg. Co., 120 F.2d at 261. In this case, the Commissioner recognized the positions of the petitioners in the preamble to the order. There was a recognition that they would be adversely affected by its conclusions. We are of the opinion that this is sufficient specificity.[9]

[9] While the activity of regulation is essentially legislative, Federal Security Administrator v. Quaker Oats Co., supra; Willapoint Oysters, Inc. v. Ewing, supra, we are not prepared to state that in an appropriate situation specific findings could not be required.

Upon a review of the record, we conclude that the Commissioner acted within his authority in promulgating the standard and definition of identity. The findings are supported by substantial evidence and the conclusions rationally follow from the findings.

The standard reflects the practice of a number of manufacturers and to those not in compliance there will be no economic hardship in complying. The fact of exclusion of the leading producers does not make the regulation unreasonable. Products have been excluded before. See, e.g., Federal Security Administrator v. Quaker Oats Co., supra. Skippy and Peter Pan will not be banned; merely a change in product formula will be required. "[I]t is an essence of legislation, functionally speaking, that in its immediate effect, it hurts some and benefits other members of society." Willapoint Oysters, Inc., v. Ewing, 174 F.2d at 694.

The order will be affirmed.

A True Copy:
Teste:

Clerk of the United States Court of Appeals for the Third Circuit.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 17689

DERBY FOODS, INC., Petitioner

v.

FOOD & DRUG ADMINISTRATION,
U.S. DEPARTMENT OF H.E.W., Respondent

Sur Petition for Rehearing

Present: HASTIE, *Chief Judge,* STALEY, FREEDMAN, SEITZ, VAN DUSEN, ALDISERT, ADAMS, and GIBBONS, *Circuit Judges.*

The petition for rehearing filed by

PETITIONER

in the above entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc, the petition for rehearing is denied.

By the Court,
[SEITZ, *Circuit Judge*]
Judge

Dated: June 22, 1970